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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,082	02/28/2002	Wolfgang Dietmaier	1803-0330-999	3192

7590

07/17/2002

PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, NY 10036

EXAMINER

MAUPIN, CHRISTINE L

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,082

Applicant(s)

DIETMAIER ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Specification Objections

The disclosure is objected to because of the following informalities: In the Brief Description of Figures, the description of Figure 6 is described in a single description. The drawings labeled Figure 6 has six distinctly separate panels labeled A-D. Each separate panel should be described for example "figures 6A through 6D" and indicated by its correct figure designation.

The following misspellings were found in the specification:

- At page 3, line 8, please delete "know" and substitute therefor with -known-.
- At page 9, line 3, please delete "Figure 6" and substitute therefor with -Figure 6A-D:-.
- At page 9, line 13, please delete "hemapoetic" and substitute therefor with -hematopietic-.
- At page 10, line 24, please delete "puffer" and substitute therefor with -buffer-
- At page 18, line 24 and 25, please delete "Figure 6" and substitute therefor with -Figure 6A-D:-.
- At page 18, line 29, please delete "without" and substitute therefor with -with-.

Appropriate correction is required.

Oath/Declaration

The oath or declaration is defective. It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application as claiming benefit to prior patented application in which the application number, filing date and the status is required. See MPEP §§ 602.01 and 602.02.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) In the instant case the language "method based on claims 1-2," is confusing because it is unclear if the method requires the step of both claims 1 and 2, or requires the steps of either claim 1 or 2.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,365,375 B1 issued 2nd April 2002. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are a species of the already issued patented claims, which, anticipates the genus. Therefore the narrower patented claims necessarily anticipate the current broader genus claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al., Proc. Natl. Acad. Sci. USA, 1992, Vol.89, pp 4857-5851 as applied to claims 1-5 above, and in view of Sorge et al., US Patent No. 5,556,772, issued 17th September 1996.

Zhang teaches a method for the amplification of nucleic acid sequences fragments from a sample with first and second thermocyclic amplification reactions with primers (page 5874, column 1), using the Taq DNA polymerase, (which also does not which possesses 3'-5' exonuclease activity). A second amplification reaction is carried out using specific primers (page 5847, column 2, second paragraph) and the first and second amplification reactions are carried out using a Taq DNA polymerase, (also see abstract page 5847 and columns 1 and 2 on the same page, and, especially the bottom of the second paragraph in column 2). Zhang further teaches multiple thermoamplification cycles of up to 50, (column 2, page 5847) and polymerase extension (see page 5847 column 2, first paragraph).

Zhang does not teach the use of two DNA polymerases.

Sorge et al., teaches a method for the amplification of nucleic acid sequences fragments from a sample using with compositions containing a mixture of two enzymes that possesses substantial 3'-5' exonuclease activity and a second DNA polymerase without 5'-3' exonuclease activity, preferably, the DNA polymerase for inclusion in the compositions are DNA polymerases that substantially lack 3'-5' exonuclease activity. (column 2 lines 58-

67, and column 7, lines 26-41, and column 8 see Example 1) Sorge also teaches that this method may be use to provide alternative methods for synthesizing polynucleotides, typically DNA (column 2, lines 26-41) and uses PCR to thermocycle (column 11, lines 19-57) with the two DNA polymerases the second DNA polymerase which does have 3'-5' activity. Sorge et al., further teaches that are considered thermostable enzymes (column 4, lines 39-44)

It would have been prima facie obvious to one having ordinary skill in the art at the invention was made to utilize the polymerase moieties of Sorge et al., in the method of Zhang, since Sorge states et al., further discloses that (column 5, lines 31-35, and column 46-47), the amplification reaction is carried out using specific primers (column 6, lines 4-5), and the combination of the DNA polymerases product a significant and unexpected amount of product cDNA products (column 12, line 37-59).

Further, it would have also been prima facie obvious to one having ordinary skill in the art at the invention was made to utilize the polymerase moieties of Sorge et al., in the method of Zhang, since Sorge states "Although compositions comprising a DNA polymerase with less 3'-5' exonuclease activity than the enzyme possessing substantial 3'-5' exonuclease activity may produce superior results in a variety of synthesis experiments, the composition is especially useful in DNA synthesis when there exists one or more mismatched nucleotide(s), particularly mismatches at the 3' end of one or more synthesis primer(s). In such situations, the results achieved, i.e., the amount of synthesis product produced, are significantly greater than the amount of synthesis product obtained using either a DNA polymerase with less 3'-5' exonuclease activity than the enzyme possessing substantial 3'-5' exonuclease activity or with a DNA polymerase possessing substantial 3'-5'

exonuclease activity alone. Other advantages of the subject compositions and methods include increased synthesis product yield, increased transcription product length, and the synthesis of polynucleotides that cannot be synthesized by a given DNA polymerase alone (column 4, lines 10-27).

Conclusion

All claims are drawn to the same claimed invention 1-4, have been rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine L. Maupin; whose telephone number is (703) 308-3617 and fax number is (703) 746-7641.

The examiner is normally in the office between the hours of 9:30 a.m. and 5:30 p.m., and telephone calls either in the morning or the mid-afternoon are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the U.S.P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 308-4242 or (703) 308-2724. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

July 12, 2002

Christine L. Maupin
Examiner
Art Unit 1637

Art Unit: 1637

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

July 12, 2002

Christine L. Maupin
Examiner
Art Unit 1637



JEFFREY FREDMAN
PRIMARY EXAMINER

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

July 12, 2002

Christine L. Maupin
Examiner
Art Unit 1637